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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,757	09/22/2006	Masaru Kimura	06662/HG	9122
1933	7590	02/18/2009	EXAMINER	
FRISHAUF, HOLTZ, GOODMAN & CHICK, PC			SZNAIDMAN, MARCOS L	
220 Fifth Avenue			ART UNIT	PAPER NUMBER
16TH Floor			1612	
NEW YORK, NY 10001-7708				
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			02/18/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/593,757	KIMURA ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	MARCOS SZNAIDMAN	1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 13 November 2008.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1,3,17,20 and 21 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1, 3, 17 and 20-21 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____.
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date _____.	6) <input type="checkbox"/> Other: _____.



## **DETAILED ACTION**

This office action is in response to applicant's reply filed on November 13, 2008.

### ***Status of Claims***

Amendment of claim 1, cancellation of claims 5, 6, 12, 13, 18 and 19, and addition of claims 20 and 21 is acknowledged.

Claims 1, 3, 17, 20 and 21 are currently pending and are the subject of this office action.

Claims 1, 3, 17, 20 and 21 are currently under examination.

### ***Priority***

The present application is a 371 of PCT/JP05/06017 filed on 03/30/2005, and claims priority to foreign application: JAPAN 2004-107084 filed on 03/31/2004.

### ***Rejections and/or Objections and Response to Arguments***

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated (Maintained Rejections and/or Objections) or newly applied (New Rejections and/or Objections, Necessitated by Amendment or New Rejections and/or Objections not

Necessitated by Amendment). They constitute the complete set presently being applied to the instant application.

***Claim Rejections - 35 USC § 103 (Maintained rejections)***

1) Claims 1, 3 and 17 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Akiya et. al. (JAPAN 2002-047208, cited in previous office action) further in view of Frandsen et. al. (Acta Chem. Scan. (1991) 45:627-631, cited in previous office action) for the same reasons that now cancelled claims 5 and 12 were rejected in the previous office action.

The limitations of now cancelled claims 5 and 12 (peroxide of an imidazole derivative) were incorporated into claims 1, 3 and 17, so the same rejection that was valid for these two cancelled claims is now incorporated into claims 1 and 3.

The reasons for these rejections have been provided in the previous office action dated August 20, 2008, the text of which is incorporated by reference herein.

Applicant's arguments have been fully considered but are not persuasive.

Applicant argues that Akiya et. al. disclose that an organic peroxide capable of generating singlet oxygen is a peroxide derived from at least one group selected from the group consisting of benzene, naphthalene, anthracene, 1,3-diene, and

cyclohexadiene type organic compounds (including natural products), and inorganic chemicals such as hydrogen peroxide.

Examiner's response: although Akiya et. al. definitively teach that the above list of compounds are the preferred ones, it is also true that Akiya et. al. teach that any peroxide capable of generating singlet oxygen upon decomposition can be used for the treatment of cancer (see for example, first sentence of paragraph [0004] and also claim 1). Although Akiya et. al. teaches a list of preferred peroxides, at no point they limit their invention to only these particular group of compounds, so it would be obvious to the skilled in the art that any peroxide capable of generating singlet oxygen can be used for the treatment of cancer with a reasonable expectation of success.

Applicant then argues that the peroxide of Frandsen (an imidazole peroxide) is not benzene, naphthalene or any of the above mentioned group of compounds that are disclosed in the Akiya reference and that Frandsen does not teach or suggest treating cancer. So the skilled would not consider combining Akiya with Frandsen.

Examiner's response: although it is true that Frandsen does not teach any of the specific group of compounds disclosed by Akiya, Frandsen does teach that imidazole peroxides (like compound 9) are capable of generating a singlet oxygen (see abstract and page 628, right column under "Thermal degradation of hydroperoxide 9 in ethanol"). So the skilled in the art will be motivated to treat cancer with any peroxide capable of generating singlet oxygen upon decomposition as taught by Akiya, including the imidazole peroxide disclosed by Frandsen or any other imidazole peroxide, since it is

expected that compounds with similar structures (imidazole peroxides) will have similar physicochemical and biological properties.

2) Claims 20-21 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Akiya et. al. (JAPAN 2002-047208, cited in previous office action) in view of Frandsen et. al. (Acta Chem. Scan. (1991) 45:627-631, cited in previous office action), and further in view of Kimura et. al. (ITE Letters on Batteries, New Technologies and Medicine (2000), 1:418-421, cited by applicant, cite in previous office action) or Tsunenaga et. al. (ITE Letters on Batteries, New Technologies and Medicine (2003), 4:633-638, cited by applicant, cited in previous office action) for the same reasons that now cancelled claims 18 and 19 were rejected in the previous office action.

The reasons for this rejection have been provided in the previous office action dated August 20, 2008, the text of which is incorporated by reference herein.

Applicant's arguments have been fully considered but are not persuasive.

Applicant argues that Kimura and Tsunenaga disclose only that peroxides of certain imidazole derivatives emit chemiluminescence, and do not teach or suggest that these peroxides are capable of generating singlet oxygen.

Examiner's response: It's true that Kimura and Tsunenaga do not teach or suggest that the disclosed peroxides are capable of generating singlet oxygen; however

Kimura and Tsunenaga teach that these compounds are imidazole peroxides, and since Frandsen teaches that imidazole peroxides are capable of generating singlet oxygen (see above discussion), it is expected that compounds with similar structural characteristics (imidazole peroxides) will have similar physicochemical and biological properties, so the skilled in the art would expect that the compounds disclosed by Kimura and Tsunenaga will be capable of generating singlet oxygen, even though Kimura and Tsunenaga are silent regarding these properties.

Applicant further argues that the instant claims provide unexpected and remarkable advantages over those disclosed in Akiya et. al.. Akiya states that increasing the temperature of an affected area of a patient with external irradiation is effective for promoting decomposition of the peroxide. In contrast thereto, the peroxides of imidazole derivatives as recited in applicants' present claims simultaneously generate both heat and singlet oxygen and thus can effectively generate singlet oxygen without heating the affected area externally.

Examiner's response: Akiya teaches that in order to promote disassembly of a peroxide, it is effective to raise the temperature of the affected part locally by means of irradiation with electromagnetic waves, etc (see paragraph [0007]), however by no means Akiya suggests or teaches that raising the temperature of the affected local part is absolutely necessary (they only say it is effective) for the treatment to be effective, but it helps in accelerating (promoting) the process. So the skilled in the art would have been motivated either to raise or not the local treated part depending on the imidazole peroxide being used.

***Withdrawn Rejections and/or Objections***

***Claim Objections***

Due to applicant's cancellation of claim 19, the claim objection is now moot.

Claim objection is withdrawn.

***Claim Rejections - 35 USC § 102***

Due to applicant's amendment of claim 1, the 35 USC 102(b) rejection is now moot.

Rejection under 35 USC 102(b) is withdrawn.

***Conclusion***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCOS SZNAIDMAN whose telephone number is (571)270-3498. The examiner can normally be reached on Monday through Thursday 8 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MARCOS SZNAIDMAN/  
Examiner, Art Unit 1612  
February 9, 2009

/Frederick Krass/  
Supervisory Patent Examiner, Art Unit 1612